UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MITCHELL R. TOLAND

Appeal 2007-2681
Application 10/680,676
Technology Center 1600

Decided: July 13, 2007

Before TONI R. SCHEINER, DONALD E. ADAMS, and ERIC GRIMES, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method for sorting plant embryos. The Examiner has rejected the claims as nonenabled and lacking adequate written description. We have jurisdiction under 35 U.S.C. § 6(b). We reverse the rejection for inadequate written description but affirm the rejection for nonenablement.

BACKGROUND

"Reproduction of selected plant varieties by tissue culture has been a commercial success for many years" (Specification 1). The predominant approach to conifer tissue culture is somatic embryogenesis, a process in which

> an explant, usually a seed or seed embryo, is placed on an initiation medium where it multiplies into a multitude of genetically identical immature embryos. . . . [T]he immature embryos are placed on a development or maturation medium where they grow into somatic analogs of mature seed embryos. These embryos are then individually selected and placed on a germination medium for further development.

(*Id.*) "[T]he selection from the maturation medium of individual embryos suitable for germination . . . is a skilled yet tedious job that is time consuming and expensive" (*id.* at 2).

The Specification discloses a method for automated sorting of embryos. Embryos are

> classified by developing a single metric classification model by acquiring raw digital image data of reference samples of whole plant embryos . . . of known embryo quality. . . . The metric values are [calculated and] divided into two sets. . . . A Lorenz curve is calculated from each set of metric values. A threshold value is determined from a point on the Lorenz curve which serves as a single metric classification model to classify plant embryos by embryo quality.

(*Id.* at 4.) The classification model developed based on embryos of known quality is then "applied to the raw image data acquired from plant embryos of unknown quality in order to classify the quality of the unknown plant embryo" (*id.*).

The Specification provides a more detailed description of the Lorenz curve method (*id.* at 18-20) and working examples of using this method to "classify[ ] embryos according to their morphological similarity to normal zygotic embryos" (*id.* at 27-30) and likelihood to germinate (*id.* at 30-32).

DISCUSSION

1. CLAIMS

Claims 1-14 are pending and on appeal. The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). We will focus on claims 1 and 14, which read as follows:

1. A method for classifying plant embryos according to their quantifiable characteristics comprising:

(a) developing a single metric classification model by

(i) acquiring raw digital image data of reference samples of whole plant embryos or any portion thereof of known quantifiable characteristics;

(ii) calculating a metric value from the acquired raw digital image data of each embryo of known quantifiable characteristics;

(iii) dividing the metric values obtained in step (a)(ii) into two sets of metric values according to their known quantifiable characteristics;

(iv) calculating a Lorenz curve from the two sets of metric values;

(v) using any point on the Lorenz curve calculated in step (a)(iv) as a threshold value to arrive at a single metric classification model for classifying plant embryos by their quantifiable characteristics;

(b) acquiring raw digital image data of a whole plant embryo or any portion thereof of unknown quantifiable characteristics; and

(c) applying the developed single metric classification model to the raw digital image data of step (b) in order to classify the plant embryo of unknown quantifiable characteristics according to its presumed quantifiable characteristics.

14. The method according to Claim 1 wherein the quantifiable characteristics comprise conversion potential, resistance to pathogens, drought resistance, heat resistance, cold resistance, salt tolerance, preference for light quality, or suitability for long-term storage.

Thus, claim 1 is directed to an automated method for classifying plant embryos. Digital images of plant embryos having known characteristics are analyzed and used to develop a "single metric classification model" for classifying other plant embryos. That is, the known samples are used to determine a "metric value" of known characteristics. The metric values are then used to calculate a Lorenz curve, which is used to determine a threshold value "to arrive at a single metric classification model."

After a single metric classification model has been generated, it is applied to digital images of a plant embryo of unknown characteristics, in order to classify the unknown embryo "according to its presumed quantifiable characteristics"; i.e., the unknown embryo is classified as similar to or dissimilar from the embryos in the training set. (Spec. 8: 17-18 ("Unclassified embryos are classified as acceptable or not based on how close images of the unclassified embryos fit to the classification model developed from the training set groups.")).

Claim 14 specifies that the "quantifiable characteristics" can be conversion potential (i.e., likelihood to germinate; Spec. 7: 13-15); resistance to pathogens, drought, heat, or cold; salt tolerance; preference for light quality; or suitability to long-term storage (i.e., storage of the embryos themselves; Spec. 7: 18). These characteristics are referred to generically as "plant embryo quality" in the Specification (*id.* at 7: 15-18).

2. PRIOR ART

The Examiner does not rely on any references.

3. WRITTEN DESCRIPTION

Claims 1-14 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking an adequate written description in the Specification. The Examiner acknowledges that the Specification describes the claimed method as applied to selecting embryos for their germination potential, but not with respect to other quantifiable characteristics:

> Appellant has demonstrated that one can take embryos which are visually determined to be good (an old and well known process), capture digital image data, and then take that data and apply well known data processing algorithms to interpret the data and produce a "classification model." It is not in the creation of a such a model that appellant has failed to adequately describe or enable in their claimed invention but in the application of said model. As such, the invention as a whole has not been adequately described or enabled.

(Answer 5.) By "good" embryos, we understand the Examiner to mean embryos having a morphology that indicates they are more likely to germinate. (See *id.*: "Using morphology as a basis for selecting embryos is old and well known – embryos of a certain morphology tend to germinate better than others.").

The Examiner argues that the Specification does not adequately describe the genus of "quantifiable characteristics" that could be selected for using the claimed method (*id.* at 5-6). The Examiner also argues that the Specification does not adequately describe "how one could practice this invention wherein a digital image of only 'any portion thereof' is captured and a model is made" (*id.* at 5). Finally, the Examiner argues that the

description is inadequate because "there is nothing to convey to one of skill in the art that the properties in claim 14 could be reasonably predicted using a digital image classification model" (*id.* at 6).

We will reverse the rejection for lack of written description. "The 'written description' requirement . . . serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed. . . . The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence." *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005).

Here, the Examiner argues that the Specification does not adequately describe the "quantifiable characteristics" to be selected for using the claimed method, relying on the test defined by *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), and cases applying it. That test, however, does not apply to every generic term recited in a claim: it applies only to a chemical genus encompassing compounds that are not defined by structure. *See Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1332, 65 USPQ2d 1385, 1398 (Fed. Cir. 2003): "Both *Eli Lilly* and *Enzo Biochem* are inapposite to this case because the claim terms at issue here are not new or unknown biological materials that ordinarily skilled artisans would easily miscomprehend."

Like the "vertebrate cells" and "mammalian cells" recited in the claims at issue in *Amgen*, the term "quantifiable characteristics" recited in the instant claims is not a "new or unknown biological material[ ] that

ordinarily skilled artisans would easily miscomprehend." As in *Amgen*, the *Eli Lilly/Enzo Biochem* test that the Examiner relies on is inapposite here.

The Examiner also argues that the claims lack adequate descriptive support because the Specification does not describe how to use images only of a "portions" of embryos to practice the claimed method or how to classify embryos according to the properties recited in claim 14 using digital image classification (Answer 5, 6).

In a nutshell, the Examiner's reasoning seems to be that the Specification does not describe these aspects of the claims because it does not provide any working examples showing classification based on embryo organs or classification with respect to the properties recited in claim 14. Lack of working examples, however, is not an adequate basis for a written description rejection. *See Falkner v. Inglis*, 448 F.3d 1357, 1366, 79 USPQ2d 1001, 1007 (Fed. Cir. 2006) ("[E]xamples are not necessary to support the adequacy of a written description[;] . . . the written description standard may be met . . . even when actual reduction to practice of an invention is absent.").

The instant Specification describes the claimed method in general terms (e.g., Specification 4 and 18-20) and provides a working example of using the method to classify embryos based on similarity to normal zygotic embryos (*id.* at 27-32). The Specification also states that the method can be used to classify embryos based on any quality susceptible to quantification (*id.* at 8: 28-29), and that images of embryo organs (i.e., portions of embryos) can be used instead of images of whole embryos (*id.* at 7: 28-35).

We reverse the rejection of claims 1-14 for lack of adequate written description because the Examiner has not adequately explained why the Specification's disclosure does not satisfy that requirement of 35 U.S.C. § 112, first paragraph. Whether it satisfies the enablement requirement of that paragraph is a separate issue, to which we now turn.

4. ENABLEMENT

Claims 1-14 also stand rejected under 35 U.S.C. § 112, first paragraph, as nonenabled. The Examiner relies in part on the same reasoning used to support the written description rejection – after explaining the rejection for lack of adequate description, the Examiner concludes that

> [i]t follows logically that the entire claimed invention has not been enabled by the instant specification because applicant has not taught how to apply the instant invention such that one of skill in the art could predict using applicant's classification model . . . whether or not any embryo would germinate or have one of the other "characteristics" as in claim 14.

(Answer 8.) The Examiner also argues that the "specification has not enabled the use of 'any portion thereof' an embryo as the means for creating a classification model" (*id.*).

Although we have some quibbles, we agree with the thrust of the Examiner's reasoning and his conclusion that the Specification does not enable practice of the full scope of the claimed method without undue experimentation.

First, the quibbles: the Examiner has not adequately supported his conclusion that more than routine experimentation would be required to use the claimed method to classify embryos on the basis of germination potential. The Examiner has acknowledged that "[u]sing morphology as a

basis for selecting embryos is old and well known – embryos of a certain morphology tend to germinate better than others" (Answer 5).

The Specification states that embryos "that are most likely to successfully germinate into normal plants are preferentially selected using a number of visually evaluated screening criteria . . . [including] axial symmetry, cotyledon development, surface texture, [and] color" (Spec. 2: 6-9). The Specification also provides working examples of the claimed method to classify embryos according to their "morphological similarity to normal zygotic embryos" (*id.* at 27: 29-30) and germination rate (*id.* at 30: 5-7).

Thus, the evidence of record appears to show that the morphological properties associated with embryos most likely to germinate into plants were well-known in the art and routinely applied by technicians in hand-sorting embryos. In light of the state of the art and the guidance and working examples presented in the Specification, the Examiner has not adequately explained why undue experimentation would be required to use the claimed method to classify embryos according to their germination potential.

We also conclude that the Examiner has not adequately explained why the claimed method could not be practiced, without undue experimentation, using digital images of portions of embryos rather than complete embryos. As shown in the application's Figure 1, the portions of a plant embryo include the cotyledon, hypocotyl, and radical. Some of the morphological properties commonly used to sort embryos are those of the embryo organs (e.g., cotyledon development; Spec. 2: 8). The Specification provides a working example of the claimed method in which the observed features used

as inputs included the "area of the cotyledons from the embryo end view, and mean area of the cotyledons touching the bounding convex hull of the embryo end view" (*id.* at 29: top line of the table).

Thus, the evidence of record appears to show that the morphological features of portions of the embryo, and not just those of the embryo overall, are important indicators of which embryos are likely to germinate. Granted, the claimed method may not be as accurate if only the features of portions of the embryo were used as inputs, but the claims do not require any particular level of accuracy. The Examiner has not adequately explained why even the claimed method could not be practiced without undue experimentation using digital images of portions of plant embryos.

That said, we agree with the Examiner's conclusion that the claims are nonenabled because the Specification provides inadequate guidance with respect to classifying embryos on the basis of characteristics other than germination potential using the claimed method. (See, e.g., Answer 6, 8-9.) Claim 14, for example, makes clear that the "quantifiable characteristics" recited in claim 1 include "resistance to pathogens, drought resistance, heat resistance, cold resistance, salt tolerance, preference for light quality, [and] suitability for long-term storage."

The Specification provides no guidance regarding what features of a digital image of embryos or embryo organs are associated with any of these characteristics. Nor does the Specification provide any working examples that show the use of embryo images to classify plant embryos according to any of characteristic other than likelihood to germinate. In fact, the evidence of record does not show there exist any features of plant embryo images that

can be used to classify embryos as resistant to pathogens, drought, etc. Therefore, we agree with the Examiner that using the claimed method to classify plant embryos according to characteristics other than likelihood to germinate would likely require undue experimentation on the part of those skilled in the art.

Appellants argue that "the present invention is *not* directed to requiring to first identify a particular set of parameters or data that can be always used as indicative of specific quantifiable characteristics of plant embryos" (Br. 9). Appellants argue that "the specification clearly describes how a single metric classification model is developed based on data acquired from reference embryos of known quantifiable characteristics, and then is used to classify embryos of unknown quantifiable characteristics according to their presumed quantifiable characteristics" (*id.* at 12).

We do not find this argument persuasive. Since the Specification does not disclose which morphological characteristics are associated with pathogen resistance, drought resistance, etc., Appellants' argument, essentially, is that disclosing a method of training a computer to recognize images of embryos that are most likely to germinate entitles them to a patent on training a computer to recognize any subset of plant embryos. Then, if it turns out that there are visually recognizable characteristics of embryos that are pathogen resistant, drought resistant, etc., Appellants' patent would cover teaching computers to recognize them, too, even though Appellants haven't disclosed (presumably because they don't know) what to train the computer to look for.

This result does not comport with the quid pro quo underlying the patent system. "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. . . . Tossing out the mere germ of an idea does not constitute enabling disclosure." *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997).

Here, Appellants have disclosed a method for using digital image data to classify plant embryos according to their likelihood to germinate. They have not, however, disclosed a method for using digital image data to classify plant embryos according to any other quantifiable characteristics. With respect to classifying embryos according to pathogen resistance, drought resistance, etc., the specification discloses nothing more than a general idea that may or may not be workable. That does not constitute an enabling disclosure and we affirm the rejection of claims 1-14 for lack of enablement.

SUMMARY

We reverse the rejection for lack of written description but affirm the rejection of claims 1-14 for lack of enablement.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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